

III. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.*, requires agencies in proposing rules, to consider the impact of those rules on small businesses. The fees implemented in this release affect contract markets (also referred to as "exchanges") and a registered futures association. The Commission has previously determined that contract markets are not "small entities" for purposes of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, 47 FR 18618 (April 30, 1982). Therefore, the Chairperson, on behalf of the Commission, certifies, pursuant to 5 U.S.C. 605(b), that the fees herein will not have a significant economic impact on a substantial number of small entities.

Issued in Washington, DC on June 2, 1999, by the Commission.

Jean A. Webb,

Secretary of the Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F-0421]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule that appeared in the **Federal Register** of January 19, 1999 (64 FR 2854). The document amended the food additive regulations to provide for the safe use of di-*tert*-butyl-*m*-cresyl phosphonite condensation product with biphenyl for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food. The document was published with an error. This document corrects that error.

DATES: This regulation is effective January 19, 1999.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 19, 1999 (64

FR 2854), FDA amended the food additive regulations to provide for the safe use of di-*tert*-butyl-*m*-cresyl phosphonite condensation product with biphenyl for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food. The nomenclature of the additive was modified to include the term "meta" (*m*). This term was placed between "butyl" and "cresyl" in the name of the subject additive and between "butyl" and "cresol" in the name of one of the starting materials to provide more accurate and descriptive names.

In the preferred chemical nomenclature, the addition of "*m*" necessitates the use of a different numbering convention in the name of the starting material than is used in the absence of "*m*". In the final rule, the agency inadvertently omitted this renumbering in the name of the starting material. Therefore, the agency is amending 21 CFR 178.2010 to correct the error.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.2010 [Amended]

2. Section 178.2010 *Antioxidants and/or stabilizers for polymers* is amended in the table in paragraph (b) in the entry for "di-*tert*-butyl-*m*-cresyl phosphonite * * *" by removing "2,4-di-*tert*-butyl-*m*-cresol" and by adding in its place "4,6-di-*tert*-butyl-*m*-cresol".

Dated: June 1, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-14518 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Decoquinatate; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a final rule that provided for adding a dry powder containing decoquinatate to whole milk to be fed to calves for prevention of coccidiosis. The document incorrectly referred to those calves as replacement calves in the heading of § 520.534(d) (21 CFR 520.534(d)) for conditions of use. This document amends the regulation to state that decoquinatate is for use in calves.

EFFECTIVE DATE: March 2, 1999.

FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 2, 1999 (64 FR 10103), FDA added § 520.534 to reflect approval of Alpharma Inc.'s new animal drug application (NADA 141-060) for use of 0.8 percent decoquinatate powder in whole milk for ruminating and nonruminating calves including veal calves. In the heading for § 520.534(d), the document incorrectly stated that decoquinatate medicated milk was for use in replacement calves. This document amends the heading for § 520.534(d) to state that decoquinatate is for use in calves by removing the word "replacement".

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.534 [Amended]

2. Section 520.534 *Decoquinatate* is amended in the heading for paragraph